NICHOLAS W. BROWN
Attorney General
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
LAURYN K. FRAAS, WSBA #53238
ANDREW R.W. HUGHES, WSBA #49515
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026-TOR PLAINTIFF STATES' REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT With Oral Argument: TBD (see ECF No. 175)

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Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

I. INTRODUCTION

FDA's response brief, like its decision to continue imposing REMS on one of the safest drugs for women's health care, ignores the facts and the law. The Court should remand this matter for FDA to determine—using the science and *only* the science—if the burdens on patient access to mifepristone should be lessened.

In attempting to avoid remand, FDA first claims that the States lack standing. But as operators of medical institutions and health care systems that provide medication abortion, state instrumentalities are directly regulated by the REMS and suffer pocketbook injuries from burdens imposed by the REMS. Next, FDA argues the States failed to exhaust their administrative remedies. But the States, medical associations, and many others have repeatedly petitioned FDA to end the mifepristone REMS, and FDA has repeatedly refused. Third, FDA claims it reasonably applied the REMS modification factors under 21 U.S.C. § 355-1(g)(4). But the record is devoid of any indication that FDA also considered the factors in 21 U.S.C. §§ 355-1(a)(1) or 355(f)(1)-(2), which govern whether FDA can single out mifepristone for unique burdens it doesn't impose on 99% of drugs. Finally, FDA insists it considered all evidence and engaged in reasoned decision making for purposes of both the APA and the Fifth Amendment. But the record reflects—and FDA now confesses—that FDA intentionally excluded entire sections of the administrative record from its review, ignored evidence that the REMS burdens patient access, failed to address concerns of major medical organizations, and refused to grapple with contrary evidence.

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Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

At bottom, while FDA congratulates itself for loosening the REMS (which it only did as a result of litigation), FDA cannot explain why it continues to treat mifepristone differently from the other 20,000 drugs that do not require a REMS. The answer is obvious: abortion. But FDA can't say that because the FDCA does not permit FDA to restrict drugs because some people disagree with how they are used. *Cf. Tummino v. Hamburg*, 936 F. Supp. 2d 162, 169 (E.D.N.Y. 2013) ("The standards are the same for aspirin and for contraceptives."). FDA's 2023 decision to continue singling out mifepristone for increased burdens was both contrary to law and arbitrary and capricious. The Court should grant the States' motion.

II. ARGUMENT

A. The States Have Standing

The States have met their burden to establish standing. At the summary judgment phase, a plaintiff must "set forth by affidavit or other evidence specific facts, . . . which for purposes of the summary judgment motion will be taken to be true," demonstrating Article III's minimum requirements. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992) (quotations omitted). The States have done that, despite FDA's halfhearted arguments to the contrary.

1. The States have demonstrated direct economic and proprietary injuries

As this Court recognized, Plaintiffs have shown injury in the form of costs fairly traceable to the 2023 REMS program. *See Washington v. FDA* (*Washington I*), 668 F. Supp. 3d 1125, 1137-38 (E.D. Wash. 2023). "Like any party, a state has

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Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

standing to challenge federal action that directly harms the state's economic interests or interferes with its operations as a service provider, market participant, or employer." *Washington v. FDA* (*Washington II*), 108 F.4th 1163, 1174 (9th Cir. 2024). Here, pocketbook injuries to the States include: (1) direct costs of complying with the 2023 REMS; and (2) costs to the States' Medicaid and other state-funded health care programs from increased surgical abortions and pregnancy care. *See id.* And because state instrumentalities are directly regulated by the REMS, they "incur these costs directly as the object[s] of regulation[.]" *Id.* at 1175. Further, as operators of medical systems, the REMS harms states' proprietary interests in providing the best possible healthcare to their patients.

Costs to Comply with the REMS. Washington and other states have demonstrated direct economic harm in the form of their costs implementing and complying with the 2023 REMS. State instrumentalities "incur these costs directly as the object of regulation[.]" *Id.* FDA concedes standing based on the costs of compliance imposed by the Pharmacy Certification ETASU, which they admit has caused "actual or imminent injury." ECF No. 170 at 16 (citing DasGupta Decl., ECF No. 4-1 at 44-47 ¶¶ 8-14, 19 (Decl. of UW Pharmacy Director)). For example, pharmacies must create costly new systems to ensure all prescribers are certified and comply with other unusual requirements. DasGupta Decl., ECF No. 4-1 at 44, 46-47 ¶¶ 8, 16, 19; *see also* Singh Decl., ECF No. 4-1 at 381-383 ¶¶ 12-14 (Decl. of UW Associate Chief Medical Information Officer). But FDA simply ignores the evidence of equivalent costly burdens imposed by the Provider Certification and

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800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

Patient Agreement Form ETASUs. For instance, the Provider Certification ETASU also necessitated setting up new secure databases and systems, including system work to ensure that telehealth appointments related to medication abortion are only scheduled with REMS-certified providers, maintaining an updated roster of certified providers for telehealth appointments (an ongoing obligation as providers come and go), teaching providers how to electronically submit their Prescriber Certification form to pharmacies, as well as the ongoing burden on prescribers of submitting their Prescriber Certification to each pharmacy they prescribe to. Singh Decl., ECF No. 4-1 at 379-382 ¶¶ 8, 10, 13; Reed Decl., ECF No. 4-1 at 327-329 ¶¶ 8-11 (UW Medicine Administrator); Godfrey Decl., ECF No. 4-1 at 97 ¶ 26 (UW OB-GYN); Shih Decl., ECF No. 4-1 at 344-345 ¶ 18 (UW OB-GYN). The same is true for compliance with the Patient Agreement Form ETASU in the telehealth context, which requires dual signatures and required custom-built processes to address confidentiality concerns in a remote setting. Singh Decl., ECF No. 4-1 at 380-31, 383-384 ¶¶ 10-11, 16-17; Reed Decl., ECF No. 4-1 at 329-330 ¶¶ 12-14; Shih Decl., ECF No. 4-1 at 343-344 ¶ 17. Washington and other States employ healthcare providers and pharmacists who prescribe and dispense mifepristone and operate instrumentalities that must spend hundreds of hours complying with *all* of the REMS's complex and highly uncommon certification requirements. *See* DasGupta Decl., ECF No. 4-1 at 43-48 ¶¶ 5-22; Singh Decl., ECF No. 4-1 at 377-385 ¶¶ 3-22; Godfrey Decl., ECF No. 4-1 at 101-102 ¶¶ 33-35; Prager Decl., ECF No. 4-1 at 275-279 ¶¶ 32-41 (UW OB-

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(206) 464-7744

GYN); Reed Decl., ECF No. 4-1 at 326-331 ¶¶ 3-17; Shih Decl., ECF No. 4-1 at 343-353 ¶¶ 15-34; *see also* Henry, et al. Decl., ECF No. 4-1 at 188-189 ¶¶ 3-8 (REMS impede WSU's ability to offer medication abortion in rural Washington); ECF No. 60 at 9-10.

Other than its concession with respect to the Pharmacy Certification requirement, FDA simply does not address the evidence regarding these expensive burdens, which are clear, direct, and establish standing as to every challenged REMS provision. *See Washington I*, 668 F. Supp. 3d at 1137-38 (holding States have shown injury in the form of unrecoverable costs fairly traceable to the REMS and have established standing).

Costs to State-Funded Health Care Programs. The States also have standing because the REMS restrictions cause more patients to seek higher-cost surgical abortion over mifepristone—resulting in increased costs to Medicaid and other state-funded healthcare programs. FDA's assertion that the States have submitted "no evidence" on this point is demonstrably false. First, the States submitted extensive evidence that the 2023 REMS restrict timely patient access to medication abortion. *See* Colwill Decl., ECF No. 4-1 at 20-23 ¶¶ 18-25; Downing Decl., ECF No. 4-1 at 65-69 ¶¶ 9-17; Godfrey Decl., ECF No. 4-1 at 87-93, 97-98 ¶¶ 17-20, 27; Gold Decl., ECF No. 4-1 at 134-139 ¶¶ 15-19, 21, 22, 24, 27; Henry, et al. Decl., ECF No. 4-1 at 189 ¶¶ 6-8; Janiak Decl., ECF No. 4-1 at 197-204 ¶¶ 15-18, 20, 22-23, 26; Lazarus Decl., ECF No. 4-1 at 220-221 ¶¶ 16-17, 19; Nichols Decl., ECF No. 4-1 at 234 ¶ 38; Prager Decl., ECF No. 4-1 at 275, 277

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800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

¶¶ 34, 38; Shih Decl., ECF No. 4-1 at 345-351 ¶¶ 20-27, 29. Any such access restrictions—whether due to a lack of certified provider (Godrey Decl., ECF No. 4-1 at 100 ¶¶ 30-31), lack of certified pharmacy (Shih Decl., ECF No. 4-1 at 349-350 ¶ 27), inability to e-sign the Patient Agreement Form (*id.* at 343-344 ¶ 17), reluctance or confusion regarding the Patient Agreement Form (Prager Decl., ECF No. 4-1 at 269 ¶ 18), lagging REMS paperwork (DasGupta Decl., ECF No. 4-1 at 44-45 ¶ 10), or some combination of these—will cause some patients to miss or forgo medication abortion altogether. The States have submitted ample evidence to this effect, *see, e.g.*, Shih Decl., ECF No. 4-1 at 343-344 ¶ 17, and its trigger of higher-cost surgical abortions (*see, e.g.*, Birch Decl., ECF No. 4-1 at 4 ¶ 10; Colwill Decl., ECF No. 4-1 at 22-23 ¶ 24; Fotinos Decl., ECF No. 4-1 at 74 ¶ 10) and pregnancy-related care (*see, e.g.*, Birch Decl., ECF No. 4-1 at 5-6 ¶¶ 15, 17; Fotinos Decl., ECF No. 4-1 at 75-76 ¶¶ 13-15).

Put simply, there is nothing at all speculative or hypothetical about the States' evidence that "[*a*]*ny* limits on the availability of medication abortion in Washington State is highly likely to cause an increase in the rate of surgical abortion" and that any such increase in costs "would be borne by Washington State." Birch Decl. ¶ 10 (emphasis added); Shih Decl. ¶ 17 ("[D]elaying the process even by a few days may make [a patient] ineligible to select medication abortion."). This is a textbook Article III injury. *See, e.g.*, *California v. Azar*, 911 F.3d 558, 571-73 (9th Cir. 2018) (states had standing based on showing that challenged agency rules would lead to more women seeking care from state-funded programs).

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800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

FDA's reliance on the Ninth Circuit's decision in *Washington II* to argue otherwise is badly misplaced. ECF No. 170 at 14. *Washington II* concerned *un*regulated parties' attempt to claim standing based on "indirect" costs. 108 F.4th at 1175. As the Court knows, Idaho and six other states tried to force their way into this suit by arguing that FDA's removal of mifepristone's in-person dispensing requirement might result in some "marginal" rate of increased complications for women taking the drug, which might, in turn, result in "follow-up care . . . 'borne by Idaho through Medicaid expenditures.'" *Id.* at 1175-76. The Ninth Circuit rejected this "highly attenuated" ground for standing. *Id.* In doing so, the court explicitly distinguished the States' "direct[]" economic harm here from Idaho's "indirect[]" injury there: "*Unlike* [*the States*], Idaho *does not* allege that it will incur these costs directly as the object of regulation[.]" *Id.* at 1175 (emphasis added). This distinction flows directly from the Supreme Court's holding that "[g]overnment regulations that require or forbid some action by the plaintiff," such as the REMS vis-à-vis States that directly provide abortion care, "almost invariably satisfy both the injury in fact and causation requirements," whereas "unregulated parties" that do not provide abortion care, "may have more difficulty establishing causation—that is, linking their asserted injuries to the government's regulation (or lack of regulation) of someone else." *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 382 (2024). *Washington II* supports, rather than refutes, standing here.

Proprietary Interests. As owners and operators of medical facilities and pharmacies, Washington and other states have proprietary interests in providing

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

the best possible healthcare to their patients—interests that are harmed by the REMS's unlawful practice restrictions. *See* ECF No. 3 at 17. FDA argues that this theory fails to identify a concrete injury because Plaintiffs do not allege, for example, "that the Patient Agreement Form actually prevents state healthcare providers from communicating what they believe is medically sound advice to patients." ECF No. 170 at 15-16. But the States' evidence says precisely what FDA claims it does not. *See, e.g.*, Godfrey Decl., ECF No. 4-1 at 82-84 ¶¶ 12-14 (Patient Agreement Form harms the patient experience and makes patient counseling more difficult because it suggests mifepristone is unsafe, when it is not); Prager Decl., ECF No. 4-1 at 269 ¶ 18. FDA next contends that Plaintiffs lack a concrete proprietary injury because they fail to "explain how state-employed prescribers who are already certified have a redressable injury stemming from the prescriber certification requirement." ECF No. 170 at 15-16. But this ignores that the REMS requires providers to send a prescriber agreement form to *every* certified pharmacy to which they send mifepristone prescriptions—plainly an ongoing burden to a provider's practice. Shih Decl., ECF No. 4-1 at 348-350 ¶¶ 23, 27; Godfrey Decl., ECF No. 4-1 at 87 ¶ 26; Colwill Decl., ECF No. 4-1 at 21 ¶¶ 19-20. Providers must also divert time to undertake other burdensome administrative tasks required by the REMS, including recording the National Drug Code and lot number for mifepristone; tracking which pharmacies are REMS certified; ensuring that telehealth appointments have digitally "dual signed" Patient Agreement forms; and coordinating with pharmacies in the event a prescription is delayed by more than

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800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

four days. *See, e.g.*, Shih Decl., ECF No. 4-1 at 341-342, 349 ¶¶ 10, 14, 27; DasGupta Decl., ECF No. 4-1 at 44-45 ¶¶ 10-11.

2. The Court should consider the States' standing as to the mifepristone REMS as a whole

Finally, FDA's request that the Court subdivide standing by individual REMS requirement is baseless. *Cf. Washington I*, 668 F. Supp. 3d at 1138 (holding that the States established standing to challenge the 2023 REMS program as a whole). To be clear, the Court need not address this argument because, as explained above, the REMS conditions operate together as a unified system that harms the States by imposing direct compliance costs, increasing State-funded healthcare costs, and interfering with the States' abilities to provide quality healthcare.

But even leaving that aside, FDA's argument still fails because the States challenge the legality of "FDA's promulgation of the mifepristone 2023 REMS" as a singular, "final agency action that is causing the States irreparable harm." *See* ECF No. 35 at 88-90. Accordingly, they ask the Court to declare unlawful and enjoin enforcement of "the mifepristone REMS" program as a whole, not as piecemeal requirements. *Id.* at 90; *Washington II*, 108 F.4th at 1172 ("[S]tanding is not dispensed in gross, . . . which means that *for all relief sought*, there must be a litigant with standing." (emphasis added) (cleaned up)). The 2023 REMS is a single regulation, and the States have standing to seek remand of all of it.

B. The Challenge Is Ripe for Judicial Review

The States' claims are ripe because FDA has repeatedly rejected arguments

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Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

that the mifepristone REMS is unsound, unsupported, and burdensome. Thus, as this Court previously found, further petitioning would be futile. *Washington I*, 668 F. Supp. 3d at 1139. Although FDA "disagrees[s] with" the Court's conclusion, it raises nearly identical arguments to those already rejected. ECF No. 170 at 16.

The evidence demonstrating exhaustion is overwhelming. First, in 2021, FDA, prompted by federal litigation, conducted a "full review" of the REMS. EAR154. Evidence submitted to FDA by the plaintiffs in that federal litigation raised all the same points States raise here: the REMS "confer no benefit in terms of safety [or] efficacy, . . . are not 'commensurate with' the risks of mifepristone, and create barriers to use that reduce patient access and negatively impact public health . . . ." EAR141. The plaintiff doctors and medical organizations also discussed the burdens associated with the Prescriber Certification and Patient Agreement ETASUs. SEAR4-6. Further, they asked for "FDA's careful consideration of the extensive evidence showing that the mifepristone REMS does not advance patient safety; causes treatment delays that undermine patients' health; subjects some patients who are unable to obtain mifepristone because of the REMS to the serious medical risks of ongoing pregnancy and childbirth; and unduly burdens both patients and the health care delivery system, with disproportionate harm to people living in rural and medically underserved areas, people with fewer financial resources, and people of color." SEAR6.

Next, in 2022, the American College of Obstetricians and Gynecologists (ACOG) and other medical professional and healthcare access organizations

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

submitted a citizen petition to FDA. EAR210-237. That petition argued, just as States do here, that the mifepristone REMS is medically unnecessary and burdensome. *See* EAR220-226. Although ACOG's petition advocated for adding miscarriage management as an indication for mifepristone, the petition also asked FDA to eliminate the REMS for *all* uses of mifepristone—not just miscarriage management. *See id.*; *contra* ECF No. 170 at 19.

These appeals are merely the latest in a longstanding chorus asking FDA to lift the REMS. *See, e.g.*, EAR38-39 (2015 letter to FDA from researchers and providers advocating for REMS removal, advising that Provider Certification "inhibits access to mifepristone" and Patient Agreement Form is "inconsistent with the requirements for other drugs with similar or greater risks"); EAR43-44 (2015 letter to FDA seeking same); EAR40-42 (2016 letter to FDA seeking same); EAR75 (2019 letter to FDA from American Academy of Physicians seeking same); EAR111-16 (2021 letter to FDA from Society of Family Planning arguing REMS "confers no benefit in terms of safety, efficacy, or acceptability . . . and instead creates barriers to use that negatively impact public health"); EAR76-80 (2020 letter to FDA explaining that "research and nearly 20 years of clinical experience have demonstrated that these requirements are medically unnecessary").

In addition to these repeated requests by the medical community, in March 2020, many of the States sent a letter to FDA explaining how "these onerous and medically unnecessary requirements limit healthcare providers' ability to

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800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

assist their female patients" and urged FDA "to act immediately and remove the FDA REMS designation." EAR69-74; *see also, e.g.*, EAR87-89 (October 2020 letter from Maryland legislators asking FDA "to consider the position of [] major medical organizations and repeal REMS both immediately and permanently"). FDA provided only a form response. ECF No. 51-11.

As the Court previously found, FDA's record of repeatedly rejecting the arguments the States raise here demonstrates beyond any serious doubt "that administrative exhaustion through a citizen petition on the January 2023 REMS would be futile." *Washington I*, 668 F. Supp. 3d at 1139; *see also El Rescate Legal Servs., Inc. v. EOIR*, 959 F.2d 742, 747 (9th Cir. 1991) ("[T]here is no requirement of exhaustion where resort to the agency would be futile."). The evidence demonstrates that FDA's position is "already set." *Id.* Thus, FDA "cannot credibly argue" that another "formal application" from States would make a difference. *Chinook Indian Nation v. Zinke*, 326 F. Supp. 3d 1128, 1144 (W.D. Wash. 2018).

FDA's contrary arguments lack merit. It claims this case involves "technical and factual assertions" that it had no opportunity to consider. ECF No. 170 at 17. This is wrong.

First, while admitting that States submitted a letter in 2020 regarding the REMS, FDA contends it didn't need to consider it, as the letter was submitted to a public docket relating to FDA's policies during COVID-19. *Id.*; EAR69-72. But the States' letter was just one of many contemporaneous letters and lawsuits urging FDA to abandon the REMS entirely. *See, e.g.*, EAR75; EAR111-16; EAR76-80;

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800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

EAR87-89. If FDA didn't consider the 2020 letter in connection with REMS modification, that only demonstrates the futility of further letter-writing.

Second, FDA complains about "points that could not have been considered in 2021," specifically, references to post-*Dobbs* events and a 2022 Canadian study. ECF No. 170 at 18-19. But FDA did not make its final REMS decision until *January 2023*, and its own record makes clear that it continued to consider evidence and information that post-dated 2021. *See, e.g.*, EAR265-268; SEAR75-78, 79-81; *see infra* 24-25. Again, if FDA failed to consider this evidence before it, that merely highlights the futility of continuing to ask.

Finally, FDA argues that ACOG's 2022 Citizen Petition did not relate to FDA's 2021 review of the REMS or its 2023 REMS modification. ECF No. 170 at 19. But FDA's 2021 review covered the same issues raised in ACOG's petition and the same issues challenged here—the Prescriber Certification form, the Patient Agreement form, and adoption of a Pharmacy Certification requirement. *See* EAR221-226. And as explained above, ACOG's petition asked FDA to remove the REMS as medically unnecessary and burdensome for *all* uses of the drug—not just miscarriage management. *See id.*; *Washington I*, 668 F. Supp. 3d at 1139.

In light of the repeated requests for REMS removal already submitted to FDA, "FDA cannot credibly argue that its decision on the Mifepristone REMS Program would change upon another citizen petition." *Id.* This challenge is therefore ripe for judicial review.

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Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

C. The 2023 REMS Is Contrary to Law

As the States previously established, the 2023 REMS is unlawful because FDA failed to apply mandatory statutory factors. ECF No. 156 at 15-19. In response, FDA doubles down on its assertion that it needs only consider the 21 U.S.C. § 355-1(g)(4) factors, arguing that it can largely ignore the other statutory REMS and ETASU factors in making a REMS modification decision. ECF No. 170 at 27-28. But this Court already rejected that argument, *Washington I*, 668 F. Supp. 3d at 1140-41, and FDA's efforts to resurrect them are unavailing.

FDA Did Not Consider the § 355-1(a)(1) Factors. Defendants concede they did not consider the § 355-1(a)(1) factors—they claim they just don't have to. But while Defendants are correct that the States "are not challenging FDA's 'initial approval' of the mifepristone REMS," ECF No. 170 at 28, this does not make the § 355-1(a)(1) factors irrelevant. In making a REMS modification decision, § 355-1(g)(4)(B) requires FDA to consider whether modification or removal of the REMS is necessary to "ensure the benefits of the drug outweigh the risks of the drug[.]" Section 355-1(a)(1) explains exactly what this means by detailing the factors FDA "shall consider" in making this determination. Even if Congress did not explicitly "cross-reference" the § 355-1(a)(1) factors in the three later sections of the REMS statute where Congress directed FDA to "ensure the benefits of the drug outweigh the risks of the drug," *see* 21 U.S.C. §§ 355-1(a)(2)(A), (g)(2)(C)(i), (g)(4)(B)(i), courts generally "presume that words used more than once in the same statute have the same meaning throughout." *In re Cybernetic Servs., Inc.*, 252 F.3d

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Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

1039, 1051 (9th Cir. 2001) (citing *Boise Cascade Corp. v. EPA*, 942 F.2d 1427, 1432 (9th Cir.1991)). Thus, when Congress directed FDA to determine whether "the benefits of the drug outweigh the risks of the drug" throughout the REMS statute, it intended the § 355-1(a)(1) factors to apply. *See* 21 U.S.C. §§ 355-1(a)(1), (a)(2)(A), (g)(2)(C)(i), (g)(4)(B)(i).

FDA nonetheless suggests it "makes[s no] sense to apply" the § 355-1(a)(1) factors to REMS modifications because many of the factors speak in predictive terms. ECF No. 170 at 28-29. But far from justifying FDA's behavior here, the predictive, uncertain nature of an initial REMS approval is *precisely why* those factors remain essential in later assessing whether a REMS should be modified or removed. It is only when making a REMS modification or removal assessment under § 355-1(g)(4)(B) that FDA has real-world data allowing it to assess whether a REMS remains necessary to ensure that "the benefits of the drug outweigh the risks . . . ." 21 U.S.C. §§ 355-1(a)(1), (g)(4)(B). Further, notwithstanding the predictive language of the factors, FDA's own guidance concedes that it "generally considers these factors in determining whether (based on new safety information) a REMS is necessary for a drug that is the subject of an approved application." SEAR89 n.24. If FDA were free to disregard the § 355-1(a)(1) factors after making its initial risk benefit/analysis, it would be able to retain a REMS forever even if real-world prescribing data later demonstrated that the congressionally mandated threshold criteria are no longer met. As this Court previously determined, that cannot be the case. *Washington I*, 668 F. Supp. 3d at 1140. By failing to consider

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800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

the six required factors, FDA acted contrary to law.

FDA Failed to Consider the § 355-1(f) Factors. FDA does not dispute it was obligated to consider the § 355-1(f) factors in the context of a REMS modification. *See* ECF No. 170 at 28 n.3. But FDA nonetheless ignores the unique and detailed requirements imposed by Congress in § 355-1(f), conflating them with those in § 355-1(g) and then arguing it "weighed precisely those factors." *See* ECF No. 170 at 29. Not so.

First, notwithstanding FDA's attempt to equate subsections (f) and (g), a quick review of the statutory language reveals that subsection (f) contains many more factors that FDA must consider. FDA made no attempt to "weigh[] precisely" these threshold factors. *Id.* Entirely absent from FDA's analysis is any determination that the mifepristone ETASUs remain "necessary . . . to mitigate a specific serious risk listed in the labeling of the drug" or are "commensurate with" any such risk, nor any determination that the medication would be "withdrawn unless" the ETASUs are in place. Indeed, the record reflects no analysis of how—given mifepristone's extensive, two-decade-long safety record—the medication continues to meet the sky-high ETASU criteria under subsection (f). That is error.

Second, while acknowledging that FDA must consider "burden[] on patient access," ECF No. 170 at 30, particularly in "rural or medically underserved areas," and must "minimize the burden on the health care delivery system" when modifying a REMS with ETASUs, FDA failed to do so. 21 U.S.C. §§ 355-1(f)(2)(C)-(D). Indeed, far from considering the issue, FDA expressly excluded

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Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

and ignored evidence on it. *Infra* 18-23. FDA's response seems to be that it acknowledged the existence of these factors, it just didn't give them any weight. For example, FDA claims it "acknowledged confidentiality concerns" regarding the prescriber certification form, but elected to soldier on regardless. ECF No. 170 at 26. And it contends it "acknowledged that the pharmacy certification requirement would likely limit the types of pharmacies that would choose to dispense mifepristone," but added it anyways. *Id.* at 27. Even crediting FDA's version of events, the statute requires FDA do more than check a box. Rather, it creates a substantive obligation on FDA to ensure ETASUs "shall . . . not be unduly burdensome . . . ." 21 U.S.C. § 355-1(f)(2)(C). FDA's lip service does not suffice.

* * *

Because FDA failed to consider mandatory statutory factors in its REMS modification decision, it is the Court's "clear duty" to reject that decision and remand for further consideration. *See S.E.C. v. Sloan*, 436 U.S. 103, 118-119 (1978) (where agency action is "inconsistent with the statutory mandate," it is a court's "clear duty" to reject it). The Court should likewise give no weight to FDA's self-serving assertion that its failure to consider the relevant statutory factors was "harmless." ECF No. 170 at 31. FDA's failure to consider statutorily required factors necessarily means its decision-making was defective under the APA, making remand the appropriate remedy. *See Sloan*, 436 U.S. at 118-119.

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800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

D. The 2023 REMS Is Arbitrary and Capricious

From ignoring evidence, to ignoring burdens, to arbitrarily singling out mifepristone for unique obstacles, FDA's 2023 REMS review was arbitrary and capricious several times over. ECF No. 156 at 19-27. FDA's response does little to address the significant gaps in its analysis and instead insists the Court not look behind the curtain, because FDA is owed near-complete deference to its decisions. ECF No. 170 at 32-35. But reasoned decision making under the APA requires more.

1. FDA excluded and ignored extensive evidence in its review

A quick review of the administrative record refutes FDA's contention that it "considered all relevant evidence before it." ECF No. 170 at 32. FDA claims that it satisfied its obligation to review all evidence in the administrative record by creating a lengthy chart listing all the materials that it intentionally *excluded* from its review. *See id.* at 32-33; EAR193-197. Indeed, FDA argues that "[t]he very existence of the chart belies Plaintiffs' contention that FDA did not 'consider' the references in the APA sense." ECF No. 170 at 33. But that is not how the APA works. To engage in reasoned decision making, an agency must "'reasonably reflect upon' and 'grapple with'" the evidence before it. *City & Cnty. of S.F. v. U.S. Citizenship & Immigr. Servs.*, 981 F.3d 742, 759 (9th Cir. 2020) (quoting *Fred Meyer Stores, Inc. v. NLRB*, 865 F.3d 630, 638 (D.C. Cir. 2017)). If that were not the case, then agencies could routinely circumvent the APA by making a list of troublesome evidence the agency decided to ignore.

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(206) 464-7744

As FDA acknowledges, among the evidence it chose to exclude was "[i]nformation from survey studies or qualitative studies that evaluated perspectives on and/or satisfaction with medical abortion procedures from patients, pharmacists, clinic staff, or providers, even if the study assessed REMS ETASUs" as well as "[d]ata on the logistics of accessing abortion care in general." EAR160-161. FDA's chart (EAR193-197) also explicitly excluded (i) a survey of "US clinicians' perspectives on how mifepristone regulations affect access to medication abortion and early pregnancy loss in primary care" (EAR122-27); (ii) a qualitative study on how the REMS "serves as the linchpin of a cycle of medication abortion stigmatization in primary care, encouraging institutional anxiety over abortion provision which leads to logistical barriers to mifepristone use" (EAR128-132); (iii) a survey of Canadian physicians finding that Canada's deregulation of mifepristone "greatly assisted primary care practitioners to implement abortion care, particularly in rural communities" (EAR133-134); (iv) a study on expanding access to medication abortion through pharmacy dispensing of mifepristone (EAR135-40); and (v) studies focused on the logistics of accessing abortion care, including a study documenting how women in underserved areas must travel increasingly far for abortion care (EAR145-47).

FDA's decision to exclude swaths of data from consideration simply because they did not provide "objective safety data," EAR160, was arbitrary and capricious because safety is not the only statutorily required consideration in a REMS review. In addition to assessing "safe use of the drug," 21 U.S.C. § 355-

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800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

1(f)(5)(B)(i), Congress directed FDA to ensure that ETASUs "are not unduly burdensome on patient access to the drug" and the "health care delivery system[.]" *Id.* §§ 355-1(f)(5)(B)(ii)-(iii). The above studies that were "excluded from the REMS review" speak directly to the burdens imposed by the REMS. EAR193-197. By myopically focusing on so-called "objective safety data" (a term FDA does not define) and excluding evidence relevant to assessing patient burden, FDA acted arbitrarily and capriciously. *See Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1206 (9th Cir. 2008) ("An agency may not ignore factors Congress explicitly required be taken into account.") (citation omitted); *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1216 (D.C. Cir. 2004) (failure to discuss a statutorily-mandated factor leaves the Court "with no alternative but to conclude that the agency failed to take account of this statutory limit on its authority, making the agency's reasoning arbitrary and capricious") (cleaned up).

Further, FDA improperly excluded from its review the positions of major professional medical organizations, including ACOG, the American Medical Association, and the American Academy of Family Physicians (AAFP), all of which advocated for removal of the REMS as medically unnecessary. EAR193; *see* EAR60 (ACOG statement recommending that mifepristone "be made available in retail pharmacies like other prescription drugs and without unique provider certification or patient consent requirements" and that removing those ETASU would "improve access"); EAR143-44 (AAFP statement explaining that REMS

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"cause significant barriers to accessing abortion care," "contributes to delays in care," and are "inconsistent with requirements for other drugs with similar or greater risks, especially in light of the significant benefit that mifepristone provides to patients"). Just like it ignored data on patient burdens, FDA purportedly excluded these "policy/advocacy statement[s]" because they did not contain "objective safety data." EAR160. But, again, Congress directed FDA to consider more than safety data. 21 U.S.C. §§ 355-1(f)(5)(B)(ii)-(iii). In its citizen petition, ACOG detailed how the Provider Certification and Pharmacy Certifications ETASUs "unduly burden[] access to the drug." EAR222-25. Yet ACOG's concerns are nowhere considered or addressed in FDA's 2023 REMS review. FDA's decision to ignore the positions of major medical organizations is particularly troubling given that FDA's own guidance permits it to "take into consideration information from a variety of sources" including from "professional societies." *See* SEAR88-89. While FDA is not required to agree with the consensus of the nation's leading medical organizations that the mifepristone REMS is unnecessary and unduly burdens patient access, reasoned decision making at least requires them to consider and "grapple with" those views. *City & Cnty. of S.F.*, 981 F.3d at 759; *see also, e.g.*, *Mayor of Baltimore v. Azar*, 973 F.3d 258, 277 (4th Cir. 2020) (HHS failed to provide satisfactory reasoning where it failed to "address head-on the arguments of" major medical organizations); *Env't Health Tr. v. FCC*, 9 F.4th 893, 908-09 (D.C. Cir. 2021) (agency acted arbitrarily and capriciously where it "failed to provide a reasoned explanation for brushing off

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Seattle, WA 98104-3188
(206) 464-7744

record evidence" from commenters including major medical organizations, and "failed even to acknowledge, let alone respond to" other health concerns).

FDA similarly ignored "stakeholder" feedback that the drug sponsors provided in August 2022. EAR266-68; *see* ECF No. 156 at 14, 22-23. As reflected in the administrative record, both Danco and GenBioPro advised FDA that "most stakeholders—particularly HCPs [health care professionals]—continue[d] to request the removal of both the Prescriber Agreement and Patient Agreement to reduce the burden on them and their patients" and that "[m]ost advocates were highly supportive to expansion to all types of pharmacies without any restrictions." EAR267. Notwithstanding that FDA specifically requested this feedback, *see* EAR266, the record is devoid of any mention or consideration of it in the agency's January 2023 decision to continue to require both the Prescriber Certification and Patient Agreement form and to impose the new Pharmacy Certification ETASU. By failing to "acknowledge, let alone respond to" this requested feedback, FDA acted arbitrarily and capriciously. *Env't Health Tr.*, 9 F.4th at 908-09.

FDA's only other response to the gaping holes in its review is that the agency did not "categorically refuse" to consider non-objective-safety-data because they considered some "provider volume" information in the context of the Patient Agreement Form ETASU. ECF No. 170 at 33. But this does not excuse FDA's failure to consider the medical studies, surveys, and data related to patient access and burdens on the health care delivery system created by the ETASUs as well as the concerns raised by major medical professional organizations. *See supra* 18-22;

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800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

see also 21 U.S.C. § 355-1(f)(5)(B)(ii). By simply listing and then not considering reams of record evidence on how the mifepristone REMS burdens patient access, and by ignoring the concerns of major medical organizations and the sponsors' stakeholder feedback, FDA failed to "pay[] attention to the advantages *and* the disadvantages of [its] decisions," *Michigan v. E.P.A.*, 576 U.S. 743, 753 (2015), ignored evidence on the statutory factors that "Congress explicitly required be taken into account," *Center for Biological Diversity*, 538 F.3d at 1206 (citation omitted), and failed to "examine the relevant data and articulate a satisfactory explanation for its action . . . ." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). This is arbitrary and capricious.

2. FDA refused to consider the safety outcomes from Canada

Notwithstanding its self-proclaimed focus on "objective safety data," FDA concedes that it did not consider *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, a study published in the New England Journal of Medicine in January 2022, a full year before FDA modified the REMS. ECF No. 170 at 33-34; *see* EAR238-239; SEAR64-74. That study examined data before and after Canada deregulated mifepristone in November 2017 and concluded that "[w]hen mifepristone became available as a normally prescribed medication in Canada," "[t]he incidences of serious adverse events and complications remained materially unchanged[.]" EAR239. The study's findings on the continued safety of mifepristone absent REMS-like conditions is consistent with the recommendations of major medical organizations that FDA excluded.

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FDA claims it was justified in ignoring the study prior to making its final REMS decision because the study was published after the agency's July 2021 literature review. ECF No. 170 at 34. FDA contends consideration of the Canadian study could lead to a "never-ending process." *Id.* This explanation fails in three ways.

First, FDA ignores that this study was brought to FDA's attention by ACOG through its October 2022 citizen petition, and was therefore "before FDA at the time it promulgated the 2023 REMS." Order, ECF No. 146 at 14; *see* EAR226. FDA did not need to do a new literature search and independently find this study before it issued its 2023 REMS decision. Instead, ACOG did that work, specifically advising FDA that the January 2022 study demonstrated that removal of the Mifepristone REMS would not harm patient safety. *Id.* Thus, FDA was on notice that the January 2022 study was relevant to its ongoing review of the REMS.

Second, FDA's attempt to use the July 2021 literature review cut-off date as a purported justification for ignoring the Canadian study also rings hollow because FDA did, in fact, consider studies brought to its attention after its July 2021 literature review. For example, on December 30, 2022, FDA wrote a memo-to-file explaining that a researcher at FDA's Center for Drug Evaluation and Research (CDER) was notified that some publications "were attached to the Complaint recently filed in a lawsuit," and that the researcher "has reviewed these five publications for the limited purpose of determining whether they contain information relevant to our review of the REMS modifications[.]" SEAR76. FDA

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800 Fifth Avenue, Suite 2000
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(206) 464-7744

concluded that the five new articles did not "include safety data relevant to the Applicants' proposed modifications to the REMS ETASUs[.]" SEAR76-77. Similarly, on January 3, 2023—the same day the REMS was approved—another CDER researcher wrote a memo to file explaining they had "received notification through a weekly email ... that a large clinical study ... was published in the Annals of Internal Medicine on January 3, 2023." SEAR79-80. FDA, once again, "reviewed this publication for the limited purpose of determining whether it contains information relevant to our review of the REMS modifications," and concluded it did not. SEAR80. These memos undermine FDA's argument that without a "cut-off date, it would never have completed its review." ECF No. 170 at 34.

Third, FDA's memo-to-file process undercuts its argument that it was free to ignore the January 2022 study simply because it was not specifically "asked to consider the Canadian study in connection with the January 2023 REMS modification." *Id.* at 34-35. As set forth above, FDA considered new information brought to its attention through various means, including outside litigation and weekly emails with research notifications. The fact that FDA was put on notice of the January 2022 study through a citizen petition by ACOG does not provide it with a basis to ignore this relevant evidence. Nor does FDA contend it was unaware of the study at the time it issued its 2023 REMS decision. *See id.* at 33-35.

In sum, rather than consider the January 2022 study, FDA ignored it. FDA's failure to consider highly relevant evidence on mifepristone's safety, published in

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800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

one of the country's most prominent medical journals and highlighted for it by a major medical association, was arbitrary and capricious. *See, e.g.*, *Port of Seattle, Wash. v. F.E.R.C.*, 499 F.3d 1016, 1035 (9th Cir. 2007) (agency's failure to consider new evidence submitted to it was arbitrary and capricious; remanding to agency for examination of the new evidence); *Catawba County, N.C. v. E.P.A.*, 571 F.3d 20, 45 (D.C. Cir. 2009) (agency "was not obliged to stop the entire process because a new piece of evidence emerged," but "[a]n agency does, however, have an obligation to deal with newly acquired evidence in some reasonable fashion") (citation omitted).

3. FDA's blinkered view of the evidence was irrational

FDA tries to justify its decision to reimpose ETASU by claiming it lacked evidence that mifepristone would be safe if the ETASU were removed. *See* ECF No. 170 at 22 (claiming FDA had no studies regarding what would happen if prescriber certification were removed), 26 (same), 27 (same), 23 (same for Patient Agreement Form). As a factual matter, this is wrong: the 2022 Canadian study demonstrated exactly that. More than that, this argument is absurd. An overwhelming body of evidence shows that mifepristone is extraordinarily safe and, indeed, safer than many commonly used drugs such as Tylenol. ECF No. 156 at 7-8. FDA has not pointed to a single scrap of evidence suggesting this is *because of* the ETASU. To state the obvious: mifepristone is safe with a REMS because it is safe. The ETASU, which are redundant of basic informed-consent and scope-of-practice norms—albeit with a lot more paperwork—are not magic guardrails

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800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

converting a drug that is too "inherent[ly] toxic[] or potential[ly] harmful" into a widely-used medication for which "serious complications have proven to be extremely rate." EAR21. Indeed, FDA effectively concedes as much by making Korlym—a higher dose of the drug—available without ETASU. ECF No. 156 at 8; *infra* 27-28.

FDA's argument proves too much. Were it true that ETASU are necessary unless FDA can point to evidence showing how the drug is prescribed in their absence, then *every* new drug would require ETASU, because at the time a drug is approved, there is generally no evidence it can be safely administered outside of a clinical trial. And of course, this would mean that all ETASUs are perpetual, because once they are in place, there generally won't be evidence showing what happens in their absence. But the ETASU statute requires more of FDA than a makeweight argument about counterfactuals—it requires a showing that the drug "is associated with a serious adverse drug experience" such that it "can be approved only if, or would be withdrawn unless" additional steps are taken "to mitigate a specific serious risk . . . ." 21 U.S.C. § 355-1(f)(1)(A). No such showing was made.

4. FDA's differential treatment of Korlym is unreasonable

FDA tries to gloss over its differential treatment of a lower dose of mifepristone when used for abortion as opposed to a higher dose when used for Cushing's disease by contending that people "with Cushing's syndrome are 'unlikely to be pregnant' due to the underlying disease, and . . . the sponsor voluntarily distributes Korlym exclusively through specialty pharmacies."

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(206) 464-7744

ECF No. 170 at 30-31 (citing DEAR22, 28). This misses the mark.

First, FDA appears to be arguing that mifepristone is less dangerous for those with Cushing's disease because those individuals are unlikely to be pregnant. *Id.* But abortion is not a serious side-effect or risk for women taking mifepristone for abortion: it is the intended purpose of the drug. *See* DEAR22.

Further, to impose an ETASU, FDA must determine that a drug has "*inherent* toxicity or potential harmfulness[.]" 21 U.S.C. § 355-1(f)(1) (emphasis added). It cannot be that a drug is "inherently" toxic or harmful to a person taking a 200-mg formulation for abortion, but not to a person taking a higher 300-mg formulation for a non-abortion indication. *See Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 28 (D.D.C. 1997) (FDA cannot treat similar products dissimilarly and cannot permit "two sets of similar products to run down two separate tracks[.]"). FDA has not shown any inherent harmfulness of mifepristone to women taking the medication for abortion—to the contrary, adverse events are "extremely rare" and even lower than for Korlym. ECF No. 156 at 5, 8; *see also* EAR149, 270. There is no reasoned basis for FDA's decision to treat an extremely safe drug differently when used for abortion versus other conditions. *See id.* at 26.27; *see also* EAR60. Yet FDA does just that. *See* EAR13 (FDA statement that Korlym approval application presented a "challenge" "because of the more controversial use of this active ingredient for medical termination of pregnancy[.]"). This differential treatment is arbitrary and capricious.

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5. FDA failed to offer a reasoned explanation for the 2023 REMS

In making its 2023 REMS decision, FDA did not apply all the statutorily required factors and inappropriately excluded portions of the record from its review. *Contra* ECF No. 170 at 20-22. For those reasons, FDA's 2023 REMS review was unlawful. In addition to those dispositive errors, FDA's own rationales for the ETASU further underscore the arbitrary and capricious nature of the 2023 REMS.

Prescriber Certification ETASU. FDA first contends it was justified in maintaining this ETASU because "the agency's literature review did not identify any studies comparing providers who met the qualifications that must be certified with providers who did not." ECF No. 170 at 22. But this asks the wrong question. As FDA concedes, the States do not dispute that mifepristone prescribers should have those qualifications; instead, the issue is whether this ETASU is necessary for prescribers who "possess those qualifications without so certifying." *Id.* at 25-26. Notably, FDA does not require prescriber certification for 99% of prescription drugs, but instead allows prescribers to self-determine if they are qualified to treat a particular condition or prescribe a specific medication based on their education and training. *See* ECF No. 156 at 2, 5 (citing state regulations and medical ethics rules that provide guardrails for prescribers; only 69 of 20,000 prescription drugs with ETASUs). The fact that FDA found no studies to support allowing *unqualified* providers to prescribe mifepristone has no bearing on whether this ETASU is necessary for *qualified* prescribers to prescribe mifepristone. FDA's reliance on its

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flawed literature review as a basis to maintain this ETASU was unreasonable.

Second, and relatedly, FDA's purported concern about the potential increase in the number of prescribers as a basis for maintaining the prescriber certification makes sense only if *unqualified* prescribers would begin prescribing mifepristone. EAR163. But the record contains no evidence to support this assumption. To the contrary, the study on which FDA relied for the potential doubling of the number of prescribers was a survey of OB-GYNs who were characterized as "well situated to provide timely abortion care." SEAR10-13; *see also* EAR120 (survey indicating providers who do not feel qualified to prescribe mifepristone do not prescribe it). Given this record evidence, FDA does not explain how an increase in the number of *qualified* OB-GYN prescribers necessitates continuation of this ETASU.

Third, FDA's determination that Prescriber Certification was needed to ensure that manufacturers learn of patient deaths ignores that mifepristone's "associated" fatality rate is a miniscule 0.0005% for the 20-plus-years it has been on the U.S. market and that not a single death can "be causally attributed to mifepristone." ECF No. 156 at 7 (citing EAR271; EAR65). Given this safety record, FDA provides no reason for continuing to single out mifepristone for this reporting that does not apply to drugs with higher death rates. *Contra* 21 U.S.C. § 355-1(f)(2)(A) (ETASU must be "commensurate" with the specific risk); *see* EAR47 ("phosphodiesterase type 5 inhibitors for the treatment of erectile dysfunction are estimated to be associated with death in up to 0.004% of users").

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Fourth, FDA contends it acknowledged the burden imposed by this ETASU on prescribers, but concluded that the burden was minimized by requiring prescribers to "certify only one time for each [sponsor]." ECF No. 170 at 26. This response completely ignores the Pharmacy Certification ETASU, which requires providers to send their certification to *every* pharmacy they send a prescription to, making the ETASU much more burdensome than FDA admits. EAR290-91.

Finally, while FDA relied on survey data from one study to support its decision to eliminate the in-person dispensing requirement because it would lead to new mifepristone prescribers, EAR166-67, in deciding to keep the prescriber certification requirement in place, FDA ignored that *same study's* finding that prescriber certification prevents nearly 10% of qualified OB-GYNs from prescribing mifepristone. EAR120-21. This was arbitrary and capricious. *Genuine Parts Co. v. E.P.A.*, 890 F.3d 304, 313 (D.C. Cir. 2018); ECF No. 156 at 23.

Patient Agreement ETASU. FDA contends that this ETASU remains necessary because it "ensures that patients are informed of the risks of serious complications associated with use of mifepristone" for medication abortion. ECF No. 170 at 23. While FDA acknowledges the States' argument that the Patient Agreement Form should be eliminated as redundant of the boxed warning in the Medication Guide, it contends that FDA considered and "rejected this argument." *Id.* at 26-27. The record, however, shows that FDA never even *considered* that the Patient Agreement Form is entirely duplicative of the risks listed in that Guide. *See* EAR163-167. Similarly, while FDA determined that the Patient Agreement Form

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800 Fifth Avenue, Suite 2000
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(206) 464-7744

"does not impose an unreasonable burden on providers or patients," EAR163, FDA nowhere addressed the sponsors' feedback that most stakeholders continued to request the removal of the Patient Agreement Form to reduce burden. EAR267.

Further, as with the Prescriber Certification, FDA found that the potential increase in the number of medication abortion providers weighed in favor of retaining the ETASU. ECF No. 170 at 24. But this does not explain why this type of redundant "patient education" (*id.*) is necessary to ensure safe use for mifepristone but not for any number of other drugs with much higher risks. And, again, it assumes that new mifepristone prescribers would be *unqualified* to explain the drug's risk to their patients. But the record does not support this assumption. *Supra* at 30. Because FDA "ignore[d] important considerations [and] relevant evidence," its rationale for continuing to impose this ETASU was unreasonable. *Rancheria v. Jewell*, 776 F.3d 706, 714 (9th Cir. 2015).

Pharmacy Certification ETASU. FDA acknowledges that its justification for this ETASU is to ensure the other REMS requirements, including Prescriber Certification, are met. ECF No. 170 at 24-25. But FDA's flawed decision to reimpose one ETASU cannot justify its decision to adopt a new one. And in adopting this ETASU, FDA completely ignored evidence that pharmacies had safely dispensed mifepristone during the COVID-19 pandemic without a Pharmacy Certification. EAR68; EAR107, 108 (zero adverse events "related to pharmacist dispensing"). FDA also claims that its cursory agreement that this ETASU would limit the types of pharmacies that would choose to dispense

mifepristone "refutes . . . that FDA ignored the burdens of this requirement." ECF No. 170 at 27. But FDA did not grapple with the evidence on this issue. It did not, for instance, consider the impact on "patients in rural or medically underserved areas" with an already limited number of pharmacies, an issue that ACOG raised (EAR225) and that Congress directed FDA to consider. 21 U.S.C. § 355-1(f). These failures too were arbitrary and capricious. *See Motor Vehicle Mfrs.*, 463 U.S. at 43.

E. Summary Judgment Is Not Warranted on the Constitutional Claim

Because FDA violated the APA, the Court need not consider the States' Fifth Amendment claim. ECF No. 156 at 27 n.1. But should the Court reach it, FDA is not entitled to summary judgment.

The States may assert the Fifth Amendment rights of staff and students at the University of Washington. *Washington v. Trump*, 847 F.3d 1151, 1159-60 (9th Cir. 2017) (successful Fifth Amendment claim). And under equal protection, FDA may not "treat[] differently persons who are in all relevant respects alike." *Nordlinger v. Hahn*, 505 U.S. 1, 10 (1992). *See also Ariz. Dream Act Coal. v. Brewer*, 757 F.3d 1053, 1064 (9th Cir. 2014) ("The groups need not be similar in all respects, but they must be similar in those respects relevant to the Defendant's policy."). Regulatory schemes are constitutionally infirm when they "irrational[ly] singl[e] out" certain conduct, or rest on a "rationale so weak" that it cannot be credited. *Merrifield v. Lockyer*, 547 F.3d 978, 991 (9th Cir. 2008).

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800 Fifth Avenue, Suite 2000
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(206) 464-7744

While public health is unquestionably a legitimate interest, it is irrational for FDA to regulate mifepristone for abortion with a rare and burdensome REMS, while imposing no REMS when the same drug is used chronically, in higher doses, for a non-abortion use. EAR2, 11, 20. And worse, FDA offers no explanation why the mifepristone REMS furthers public health when far more dangerous drugs are widely available without a REMS and even without a prescription. *See, e.g.*, EAR84, 144 (higher complication and death rates for Tylenol, aspirin, penicillin, and Viagra). FDA transparently singled out abortion providers and student patients for worse treatment because it believes abortion is "controversial." EAR13. That fails even rational basis review.

F. The Court Should Remand with Guardrails to Protect the Status Quo

As this Court previously recognized, when an agency violates the APA, "'[o]rdinarily . . . the regulation is invalid,'" and the remedy is to "reinstate the rule previously in force." *Washington I*, 668 F. Supp. 3d at 1143 (citations omitted). Here, the States sought remand and not vacatur because of the potentially disruptive consequences of vacatur. *See id.*; ECF No. 156 at 27. While the States continue to believe this is the appropriate remedy, it is critical that the status quo be maintained on remand while FDA determines if the 2023 REMS can be removed or made less burdensome. Otherwise, FDA would be free to immediately kowtow to political pressure to make the mifepristone REMS even more burdensome. Indeed, at his confirmation hearing, HHS Secretary Robert F. Kennedy Jr. promised to implement "[w]hatever" position President Trump takes

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800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

on "how to regulate" mifepristone. https://tinyurl.com/3htfk62n (Fraas Decl., Ex. 4). And recent news reports indicate that those who advocated in support of FDA's decisions to loosen certain restrictions on mifepristone are being forced out on those very grounds. https://tinyurl.com/2p8264r7 (Fraas Decl., Ex. 5). Given these indications of improper politicalization at FDA, guardrails are imperative. *See N.C. Fisheries Ass'n, Inc. v. Gutierrez*, 550 F.3d 16, 20 (D.C. Cir. 2008) (explaining that "detailed remedial orders" are permissible in "extraordinary circumstances"). Accordingly, this Court should issue a narrow injunction requiring FDA to maintain the status quo while FDA completes its review of the excluded and ignored evidence and consideration of all relevant statutory factors on remand. *Doe v. Rumsfeld*, 341 F. Supp. 2d 1, 16 (D.D.C. 2004) (issuing injunctive relief in conjunction with remand to FDA). Further, the Court should keep this case open "to ensure that, if the need arises, further action could be taken by the Court." *See Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479, 487 (D. Md. 2019).

III. CONCLUSION

The Court should grant summary judgment for the States, deny FDA's motion for summary judgment, and remand to FDA with an injunction maintaining the status quo during the remand period.

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

DATED this 31st day of March 2025.

NICHOLAS W. BROWN
Attorney General

s/ Lauryn K. Fraas
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
LAURYN K. FRAAS, WSBA #53238
ANDREW R.W. HUGHES, WSBA #49515
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744
Noah.Purcell@atg.wa.gov
Colleen.Melody@atg.wa.gov
Lauryn.Fraas@atg.wa.gov
Andrew.Hughes@atg.wa.gov
Tera.Heintz@atg.wa.gov
Attorneys for Plaintiff State of Washington

DAN RAYFIELD
Attorney General of Oregon

s/ Carla A. Scott
SANDER MARCUS HULL, WSBA #35986
CARLA A. SCOTT, WSBA #39947
Senior Assistant Attorneys General
YOUNGWOO JOH, OSB #164105
Assistant Attorney General
Trial Attorneys
Tel: (971) 673-1880
Fax: (971) 673-5000
marcus.hull@doj.state.or.us
carla.a.scott@doj.state.or.us
youngwoo.joh@doj.state.or.us
Attorneys for State of Oregon

KRIS MAYES
Attorney General of Arizona

s/ Daniel C. Barr
Daniel C. Barr (Arizona No. 010149)
Chief Deputy Attorney General
Luci D. Davis (Arizona No. 35347)
Office of the Attorney General of Arizona
2005 N. Central Ave.
Phoenix, AZ 85004-1592
Phone: (602) 542-8080
Email: Daniel.Barr@azag.gov
Luci.Davis@azag.gov
Attorneys for Plaintiff State of Arizona

PHILIP J. WEISER
Attorney General of Colorado

s/ Shannon Wells Stevenson
SHANNON WELLS STEVENSON, #35542
Solicitor General
MICHAEL MCMASTER, CO #42368
Assistant Solicitor General
Office of the Attorney General
Colorado Department of Law
1300 Broadway, 10th Floor
Denver, CO 80203
Phone: (720) 508-6000
Attorneys for Plaintiff State of Colorado

WILLIAM TONG
Attorney General of Connecticut

s/ Alma Rose Nunley
Alma Rose Nunley
Assistant Attorney General
Office of the Connecticut Attorney General
165 Capitol Avenue
Hartford, CT 06106
alma.nunley@ct.gov
(860) 808-5050
Fax: (860) 808-5347
Attorney for Plaintiff State of Connecticut

KATHLEEN JENNINGS
Attorney General of Delaware

s/ Vanessa L. Kassab
VANESSA L. KASSAB
Deputy Attorney General
Delaware Department of Justice
820 N. French Street
Wilmington, DE 19801
302-683-8899
vanessa.kassab@delaware.gov
Attorney for Plaintiff State of Delaware

KWAME RAOUL
Attorney General of Illinois

s/ Caitlyn G. McEllis
Caitlyn G. McEllis (6306561)
Senior Policy Counsel
Office of the Illinois Attorney General
115 South LaSalle Street
Chicago, IL 60603
Phone: (312) 793-2394
Caitlyn.McEllis@ilag.gov
Attorney for Plaintiff State of Illinois

DANA NESSEL
Attorney General of Michigan

s/ Stephanie M. Service
Stephanie M. Service (P73305)
Assistant Attorney General
Michigan Department of Attorney General
Health, Education & Family
Services Division
P.O. Box 30758
Lansing, MI 48909
(517) 335-7603
ServiceS3@michigan.gov
Attorney for Plaintiff Attorney General of Michigan

AARON D. FORD
Attorney General

s/ Heidi Parry Stern
Heidi Parry Stern (Bar. No. 8873)
Solicitor General
Office of the Nevada Attorney General
1 State of Nevada Way, Ste. 100
Las Vegas, NV 89119
HStern@ag.nv.gov
Attorney for Plaintiff State of Nevada

RAÚL TORREZ
Attorney General of New Mexico

s/ Aletheia Allen
Aletheia Allen
Solicitor General
Executive Office
State of New Mexico Department of Justice
201 Third St. NW, Suite 300
Albuquerque, NM 87102
505-527-2776
AAllen@nmag.gov
Attorney for Plaintiff State of New Mexico

PETER F. NERONHA
Attorney General of Rhode Island

s/ Julia C. Harvey
JULIA C. HARVEY #10529
Special Assistant Attorney General
150 S. Main Street
Providence, RI 02903
(401) 274-4400 x2103
Attorney for Plaintiff State of Rhode Island

CHARITY R. CLARK
Attorney General of Vermont

s/ Douglas Keehn
DOUGLAS KEEHN
Assistant Attorney General
109 State Street
Montpelier, VT 05609-1001
(802) 793-3892
douglas.keehn@vermont.gov
Attorney for Plaintiff State of Vermont

BRIAN L. SCHWALB
Attorney General for the District of Columbia
COTY MONTAG
Deputy Attorney General
Public Advocacy Division
WILLIAM STEPHENS
Assistant Deputy Attorney General
Public Advocacy Division

/s/ Nicole S. Hill
NICOLE S. HILL
Assistant Attorney General
Office of the Attorney General for the District of Columbia
400 Sixth Street, N.W.
Washington, D.C. 20001
(202) 727-4171
nicole.hill@dc.gov
Attorneys for Plaintiff District of Columbia

ANNE E. LOPEZ
Attorney General

s/ Erin N. Lau
Erin N. Lau 009887
465 South King St., Room 200
Honolulu, Hawaii 96813
Erin.N.Lau@hawaii.gov
Counsel for the State of Hawaii

AARON M. FREY
Attorney General

s/ Halliday Moncure
Halliday Moncure, Bar No. 4559
Assistant Attorney General
Office of the Maine Attorney General
6 State House Station
Augusta, ME 04333-0006
(207) 626-8800
halliday.moncure@maine.gov

ANTHONY G. BROWN
Attorney General of Maryland

s/ Joshua M. Segal
JOSHUA M. SEGAL
Principal Deputy Solicitor General
Office of the Attorney General of Maryland
200 Saint Paul Place, 20th Floor
Baltimore, Maryland 21202
(410) 576-6446
jsegal@oag.state.md.us
Attorney for Plaintiff State of Maryland

KEITH ELLISON
Attorney General
State of Minnesota

s/ Liz Kramer
LIZ KRAMER (#0325089)
Solicitor General
ANNA VEIT-CARTER (#0392518)
Assistant Attorney General
445 Minnesota Street, Suite 1400
St. Paul, Minnesota 55101-2131
(651) 757-1010 (Voice)
(651) 282-5832 (Fax)
liz.kramer@ag.state.mn.us
anna.veit-carter @ag.state.mn.us
Attorneys for Plaintiff State of Minnesota

Pennsylvania Governor's Office of General Counsel

s/ Michael J. Fischer
MICHAEL J. FISCHER, Pa. Bar No. 322311
Executive Deputy General Counsel
AIMEE D. THOMSON, Pa. Bar No. 326328
Deputy General Counsel
Office of General Counsel
30 N. 3rd St., Suite 200
Harrisburg, PA 17101
(717) 831-2847
mjfischer@pa.gov
aimeethomson@pa.gov
Attorneys for the Commonwealth of Pennsylvania

CERTIFICATE OF SERVICE

I hereby certify that on March 31, 2025, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF System, which in turn automatically generated a Notice of Electronic Filing (NEF) to all parties in the case who are registered users of the CM/ECF system. The NEF for the foregoing specifically identifies recipients of electronic notice.

I declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

DATED this 31st day of March 2025, at Seattle, Washington.

s/ Lauryn K. Fraas
LAURYN K. FRAAS, WSBA #53238
Assistant Attorney General